



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,892	06/30/2000	Perry D. Haaland	P-4948	2067

7590

04/17/2003

Richard J Rodrick
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 04/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/608,892

Applicant(s)

HAALAND ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12-18, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 4, 15-18, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1639

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-3 and 12-14 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that claims 4 and 15-18 should be recombined with group I since the cell culture medium contains the peptides of claim 1. The search performed for the peptides of claim 1, will be a search for the use of the peptides in cell culture medium which will not be unduly burdensome. This is not found persuasive because a search for a peptide does not necessarily accompany the cell culture, which contains the peptide. The peptide can be made by chemical synthesis, not necessarily by cell culture. Applicants urge the group to which claims 4, 15-19 should belong. These claims should properly be grouped with Group IV, i.e., a cell culture is employed in the method of identifying a peptide that can be obtained from a peptide library. [The confusion created by the restriction requirement is regretted.]

The requirement is still deemed proper and is therefore made FINAL.

Newly submitted claims 31-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are the

Art Unit: 1639

originally non-elected method of producing the peptide which was grouped as group IV i.e., claims 26-29 which have been cancelled in the Amendment of 6/12/02.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

Claims 1-3 and 12-14 are under examination.

Claims 4, 15-18 and 31-32 are withdrawn from examination as being drawn to the non-elected inventions.

Claims 5-11 and 19-30 have been cancelled in the Amendment of 6/12/02.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

Art Unit: 1639

which applicant regards as the invention for reasons set forth in the last Office action.

A). Applicants argue that the specification at page 3, lines 32-32 and again at page 5, lines 1-5 recites that the peptides may be produced either chemically or recombinantly. However, the method by which the peptide is produced does not further characterize or limit the peptide per se. This is especially so, since the primary structure of the peptide is already defined. Applicants' argument as to the degeneracy of the genetic code is unclear and irrelevant to a peptide that has already been encoded by the nucleic acid.

B). Applicants urge that claims 3 and 14 have been amended. However, this does not obviate the rejection of the claims. Since as stated in the last Office action, claim 1 does not recite a concatemer of the peptide, rather only a peptide. Furthermore, it is not clear as to the method by which the recombinant nucleic acid is expressed or the components necessary for its expression. This is a process step that does not further limit the compound (peptide) claim or does not add further characterization to the peptide.

Amended claim 14 does not further limit claim 13 since the limitations recited in claim 14 is already present in claim 13.

Art Unit: 1639

C). Applicants argue that claim 12 has been amended that obviates the rejection. However, claim 12 is still indefinite as to the language ".....selected peptide from a library" i.e., it requires a step as to how the peptides have been selected from the library. This claim recites two statutory subject matter i.e., selection of the peptide from the library and the selected peptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 1639

Claims 1-2 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Wei et al for reasons advanced in the last Office action.

Applicants admit that Wei teaches that the polypeptides of the invention include the polypeptide of Seq. ID. No. 2, which is the deduced amino acid sequence of hMutT2 or biologically active portions thereof containing at least 30 amino acids and preferably 50 amino acids. But argue that the polypeptides of Wei et al contain at least 30 amino acids and must have the biological functionality of the full polypeptide. In response, it is well settled law that claims should be given its reasonable broadest interpretation. There is nothing in the claims that limit the peptide to the argued length of the peptide. Claim 3, which contains a concatemer, is anticipated by the specific peptide of at least 30 amino acids. Also, claim 12 of undefined peptide structure is anticipated by the 30-mer peptide of Wei. Furthermore, in treating a disease associated with errors in DNA replication, as Wei discloses, is equivalent, if not the same, to the argued cell growth. Inhibition of cell growth results in the treatment of cell responsible for the growth. Accordingly, the specific polypeptide of Wei containing specific residues anticipates the broadly claimed peptide without any defined structure as in claim 12 or claim to

Art Unit: 1639

a concatemer having other undefined amino acid residues in the FEFVG sequence.

Wei in the Examples discloses claims 2-3 drawn to a recombinant method of making the peptide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wei et al for reasons set forth in the last Office action.

Applicants argue that the examiner's assertion of motivation to make the selected fragment of applicant's invention from the larger polypeptide protein (sic, is it a protein or a polypeptide?) is hindsight, which is inappropriate.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based

Art Unit: 1639

upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, Wei positively discloses not only the 30-mer peptide but its biologically active portions. It would be within the ordinary skill in the art to determine which of the short length polypeptide, 30-mer, the portions that are biologically active. In the absence of new and unexpected results of the claimed 5-mer peptide over the 30-mer or biologically active portions of Wei, the claimed peptide fragment is prima facie obvious.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS**

Art Unit: 1639

of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

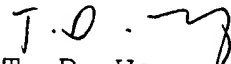
Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Application/Control Number: 09/608,892

Page 10

Art Unit: 1639

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw

April 14, 2003